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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
FOX, DAVID T	

ART UNIT	PAPER NUMBER
1638	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/576,693	KUBO ET AL.	
	Examiner	Art Unit	
	David T. Fox	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *13-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☒ Claim(s) *5-12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 January 2007* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/21/06 & 3/4/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Restriction/Election

Applicant's election with traverse of Group I in the reply filed on 10 November 2008 is acknowledged. The traversal is on the ground(s) that the claims are all closely related by the same nucleic acid compositions and methods for their use, and thus would require no burdensome search. This is not found persuasive because the different groups require a multitude of divergent starting materials and method steps, each not required by the other, including methods of bacterial transformation, methods of gene sequencing, methods of molecular marker identification, etc., as stated previously. Each of these starting materials and method steps would require a separate and burdensome search.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-12 are elected, and claims 1-4 are subject to examination, as indicated below.

Claims 13-30 are withdrawn as being drawn to non-elected subject matter.

Claim Objection

Claims 5-12 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend upon another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Drawing Objection

Figures 3 and 7 are objected to because they are solid black and indecipherable.

Effective Filing Date

The effective filing date of the claimed invention is 24 December 2003, the filing date of the foreign priority document, which disclosed all elements of the claimed invention.

Information Disclosure Statement

The foreign patent and non-patent literature documents listed on the Information Disclosure Statement of 21 April 2006 have not been received. The Examiner has separately retrieved the Olszewski et al reference, and cited it on the Notice of References cited. All other foreign patent and non-patent literature documents listed on the IDS of 21 April 2006 should be resubmitted for consideration, together with a new IDS listing them.

Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Kawasaki (US 6,521,408, Applicant cited).

The claim is drawn to a method for screening genomic fragments comprising cloning plant genomic DNA into a library, introducing each genomic fragment from the library into a plant to produce a transgenic plant, cultivating the transgenic plant or its

progeny to select a plant with an agriculturally advantageous phenotype, and selecting the genomic DNA responsible for said phenotype.

The specification broadly defines "agriculturally advantageous" as any "quantitative increase or decrease of a plant or a part of a plant, or an increase or decrease in growth rate of a plant or a part of a plant" (page 16, paragraph immediately below the heading "Description of Terms"), including "higher vigor of the entire plant, larger plant and organs, ...greater resistance to diseases and pests, greater resistance to various environmental stresses..., increase or decrease in a specific component, [and] increase or decrease in a specific enzyme activity" (page 17 of the specification, paragraph [0036]).

The specification broadly defines "selection" as including the subjecting of a population of individual plants to selection to the point where no plants remain that comply with the selection criteria; wherein no further experimental input is necessary (paragraph bridging pages 17 of the specification, paragraph [0038]). The specification does not provide a separate definition of "selection" as it applies to genomic fragments *per se*.

Kawasaki teaches a method of plant transformation with *Agrobacterium* cells comprising genomic fragments contained in a genomic library, wherein the plant to be transformed is deficient in some function, followed by selection of transformed plants which exhibit a restored function due to the presence of a particular genomic fragment, wherein those transformed plants exhibiting the restored function are identified as containing the genomic fragment (see, e.g., claim 1). Given the broad definition of

"agriculturally advantageous" above, it appears that any restoration of function would inherently result in either an increase in enzymatic activity or "component" production, due to the presence in the genomic fragment of a gene encoding said enzyme or "component". Once the transformed plants exhibiting the restoration of the function are identified, the remaining plants will not exhibit that function restoration.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Lazo et al (1991, Bio/Technology 9: 963-967, previously cited by Examiner).

Claim 2 is drawn to the method of claim 1 wherein the genomic DNA fragment is at least 1 kb in size and is insertable into a cloning vector.

Lazo et al teach a method of plant transformation with *Agrobacterium* comprising phage cosmid cloning vectors comprising 15-20 kb fragments of *Arabidopsis* genomic DNA, wherein plants transformed therewith exhibited the agriculturally advantageous trait of herbicide resistance, and wherein successive testing of progeny allows the identification of the particular genomic clone conferring the resistance, i.e. the selection of the particular genomic fragment. See, e.g., paragraph bridging pages 965 and 966; page 966, Figure 2; paragraph bridging pages 966 and 967.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Olszewski et al (1988, Nucleic Acids Research 16: 10765-10782).

Claims 3-4 are drawn to the method of claims 1 or 2 wherein the genomic DNA fragment is first inserted into a plant cell via biological means, followed by regeneration of a whole transgenic plant from the transgenic plant cell.

Olszewski et al teach the biological transformation of tobacco cells with an *Agrobacterium* bacterial strain comprising a plasmid comprising 15-20 kb of *Arabidopsis* genomic DNA, wherein the genomic DNA fragments were cloned in cosmid vectors and then transferred to *Agrobacterium*, wherein whole tobacco plants were regenerated from the transformed cells, wherein genomic DNA was isolated from the transgenic plants, and wherein the genomic DNA fragment correlated with improved growth in the presence of herbicide was selected. See, e.g., page 10768, first, third and fourth full paragraphs; page 10769, second and third paragraphs; page 10770, Figure 1; page 10771, Figure 2 and penultimate paragraph; paragraph bridging pages 10774 and 10775; page 10775, penultimate paragraph; page 10776, penultimate paragraph.

Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawasaki et al (US 6,521,408) in view of Hamilton et al (1999, The Plant Journal 18: 223-229); further in view of Frary et al (1996, Plant Cell Reports 16: 235-240), further in view of Tigchelaar et al (1978, HortScience 13: 508-513).

Kawasaki et al teach a method of biological plant transformation with *Agrobacterium* containing genomic fragments from a plant genomic DNA library, wherein transformed plants exhibiting a trait conferred by a gene in said genomic fragments are identified, as discussed above.

Kawasaki et al also teach the broad applicability of their method to identify and isolate various plant genes present in 10 kb or larger genomic fragments, in particular genes involved in agricultural traits, for the transformation of monocotyledonous or dicotyledonous plants, wherein the genomic DNA containing the gene conferring said trait may be identified by transformation of plants deficient in that trait (see, e.g., column 2, lines 14-21, 26-28, 43-53, 59-67; column 3, lines 1-10 and 13-15; column 4, lines 43-58; column 5, lines 27-30 and 50-55; column 6, lines 10-40; column 7, lines 12-19 and 43-57; column 11, lines 57-61; column 12, lines 59-67; column 13, lines 1-5).

Kawasaki et al do not teach the transformation of isolated plant cells or plant cell cultures, followed by regeneration of a whole transformed plant therefrom.

Hamilton et al teach the production of tomato genomic DNA fragments, at least 100 kb in size, in a library of cloning/plant transformation *Agrobacterium* vectors, for the

identification of agricultural genes of interest via tomato transformation therewith via phenotypic complementation, wherein the tomato transformation method of Frary et al was employed (see, e.g., page 223, column 2, penultimate paragraph; paragraph bridging pages 223 and 224; page 224; page 227, column 1, second and third paragraphs, column 2, penultimate paragraph).

Frary et al teach the *Agrobacterium*-mediated transformation of tomato tissue explants containing cells, followed by the regeneration of whole transgenic tomato plants (see, e.g., page 235, column 2; page 236, column 1, top two paragraphs; page 239, Figure 4).

Tigchelaar et al teach tomato mutants with delayed ripening, due to the mutation of ripening genes, wherein ripening involves the degradation of fruit tissue by the enzyme polygalacturonase, and the production of carotenoid compounds and flavor-conferring compounds (see, e.g., paragraph bridging pages 508 and 509; page 511, column 2, Figure 1). Said ripening process of plant part decrease and compound production meets Applicant's definition of an "agriculturally advantageous" trait.

It would have been obvious to one of ordinary skill in the art to utilize the transformation-mediated method of plant transformation with genomic DNA fragments from a DNA library taught by Kawasaki, and to modify that method by incorporating the tomato genomic DNA library taught by Hamilton et al, the *Agrobacterium*-mediated tomato transformation method taught by Frary et al, and the tomato ripening mutant plants taught by Tigchelaar et al, for the selection of those genomic clones containing ripening genes; given the suggestion by Kawasaki to broadly apply their methods to

dicotyledonous plants (which includes tomato), and the suggestion by Hamilton et al to utilize the *Agrobacterium*-mediated transformation of plants with plant genomic fragments for the identification of new agriculturally advantageous genes via phenotypic complementation.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamilton (US 5,977,439) in view of Hamilton et al (1999, The Plant Journal 18: 223-229); further in view of Frary et al (1996, Plant Cell Reports 16: 235-240), further in view of Tigchelaar et al (1978, HortScience 13: 508-513).

Hamilton teach a cloning vector comprising large fragments of tomato genomic DNA contained in a genomic library, and suggest *Agrobacterium*-mediated tomato transformation therewith for the identification of agriculturally advantageous genes from said genomic fragments via phenotype complementation, wherein the genomic fragment containing the agriculturally advantageous gene can be identified and isolated (see, e.g., column 1, lines 24-27; column 2, lines 51-65; column 3, lines 1-3 and 13-41; column 5, lines 13-25; column 7, lines 35-48; column 8, line 61 through column 9, line 28; column 10, line 61 through column 11, line 34).

Hamilton does not teach tomato transformation.

Hamilton et al teach *Agrobacterium*-mediated tomato transformation with a vector comprising large genomic DNA fragments, for the identification of agriculturally advantageous genes via phenotype complementation, as discussed above.

Frary et al teach an *Agrobacterium*-mediated method of tomato cell transformation, followed by the regeneration of whole transgenic tomato plants, as discussed above.

Tigchelaar et al teach mutant tomato plants with delayed fruit ripening as discussed above.

It would have been obvious to one of ordinary skill in the art to utilize the transformation-mediated method of plant transformation with tomato genomic DNA fragments from a DNA library taught by Hamilton, and to modify that method by incorporating the tomato genomic DNA library taught by Hamilton et al, the *Agrobacterium*-mediated tomato transformation method taught by Frary et al, and the tomato ripening mutant plants taught by Tigchelaar et al, for the selection of those genomic clones containing ripening genes; given the suggestion by Hamilton to broadly apply her methods to dicotyledonous plants including tomato, and the suggestion by Hamilton et al to utilize the *Agrobacterium*-mediated transformation of plants with plant genomic fragments for the identification of new genes via phenotypic complementation.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lazo et al in view of Valvekens et al (1988, Proc. Natl. Acad. Sci. USA 85: 5536-5540), further in view of Haughn et al (1986, Molecular and General Genetics 204: 430-434).

Lazo et al teach *Agrobacterium*-mediated transformation of herbicide-sensitive *Arabidopsis* plants with genomic libraries comprising 15-20 kb genomic DNA fragments, some of which comprise a putative herbicide-resistance gene from the herbicide-resistant GH50 *Arabidopsis* strain, for the identification of the particular genomic

fragment containing the herbicide resistance gene via phenotypic complementation, followed by the selection of the genomic fragment for the further isolation of the gene. See, e.g., page 963, column 1, bottom paragraph; page 965, column 2, bottom paragraph; page 966, paragraph bridging columns 1 and 2; paragraph bridging pages 966 and 967.

Lazo et al do not teach the transformation of *Arabidopsis* cells followed by the regeneration of whole transgenic *Arabidopsis* plants therefrom.

Valvekens et al teach an *Agrobacterium*-mediated method of *Arabidopsis* root tissue comprising cells, followed by the regeneration of whole transformed *Arabidopsis* plants from the transformed cells. See, e.g., paragraph bridging pages 5536 and 5537; page 5537, Figure 2.

Haughn et al teach the herbicide-resistant Arabidopsis strain GH50 (see, e.g., page 430, column 2, second and third full paragraphs; page 431, column 2, second and third full paragraphs).

It would have been obvious to one of ordinary skill in the art to utilize the *Agrobacterium*-mediated transformation of herbicide-sensitive *Arabidopsis* plants with genomic DNA fragments as taught by Lazo et al, and to modify that method by incorporating the particular transformation method of Valvekens et al and the genomic fragments from the herbicide-resistant *Arabidopsis* strain GH50, to identify and select the herbicide resistance gene from the genomic clones containing it, as suggested by Lazo et al. Choice of known method of *Arabidopsis* transformation would have been the optimization of process parameters. The herbicide resistance gene confers increased

plant growth and resistance to environmental (chemical) stress, thus meeting Applicant's definition of an agriculturally advantageous gene.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David T Fox/

Primary Examiner, Art Unit 1638

February 16, 2009